

REMARKS

Claims 1-31 and 34-35 were pending in this application. Claim 25 is herein withdrawn. Upon entrance of this amendment, claims 1-24, 26-31 and 34-35 will remain pending. Claim 35 is herein amended. *No new matter is added.*

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1-24, 26-31 and 34-45 stand rejected under 35 U.S.C. § 103(a) on the basis that they are unpatentable over WO 2001/95910 (hereinafter “Yu *et al.*”) in view of WO 2004/026843 (hereinafter “Carter *et al.*”). Particularly, it is asserted that Carter *et al.* teaches benzodiazepine derivatives, such as (S)-1-(2-fluorophenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3yl)urea, in pharmaceutical compositions which are effective against RSV and that the benzodiazepine derivatives can be combined with other anti-viral compounds. It is also asserted that Yu *et al.* teaches compounds, such as 1-cyclopropyl-3-[1-(4-hydroxybutyl)-1H-benzimidazol-2-ylmethyl]-1,3-dihydro-imidazo[4,5-c]pyridine-2-one, which are effective for treatment of the RSV. Applicants respectfully disagree.

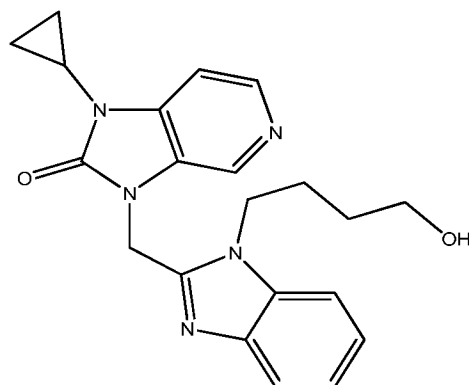
The Examiner correctly notes that Yu *et al.* does not teach that the compounds disclosed therein can be combined with a benzodiazepine derivative capable of inhibiting RSV replication. However, it is asserted that Carter *et al.* cures this deficiency. Applicants respectfully disagree.

Applicants respectfully submit that although it is true that Carter *et al.* teaches the elected benzodiazepine compound, (S)-1-(2-fluorophenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3yl)urea, Carter *et al.* does not disclose the *combination* of benzodiazepine with other anti-viral compounds *for the treatment of RSV* as asserted in the Office Action. Rather, Carter *et al.* (p. 36, lines 22-28) discloses a “combination of a compound of formula (I), or a pharmaceutically acceptable salt thereof, with an *anti-influenza compound* and the use of such a combination in the treatment of *concomitant RSV and influenza infections.*” Applicants note that the disclosed composition includes benzodiazepine and an *anti-influenza*. By contrast and in distinction from Carter *et al.*, the present invention claims a composition

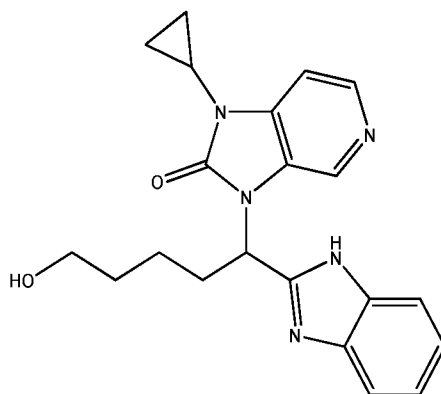
comprising a benzodiazepine derivative for inhibiting RSV replication and an inhibitor of the RSV fusion protein.

Accordingly, Carter *et al.* does not teach or suggest the combination of a benzodiazepine derivative for inhibiting RSV replication and an inhibitor of the RSV fusion protein. One of ordinary skill in the art would not have been motivated by the combination of a benzodiazepine and anti-influenza compound, as disclosed in Carter *et al.*, to combine the benzodiazepine with an inhibitor of the RSV fusion protein.

Applicants also note that the compound cited in the Office Action as being disclosed by Yu *et al.* at Example 73 is 1-cyclopropyl-3-((1-(4-hydroxybutyl)-1H-benzo[d]imidazol-2-yl)methyl)-1H-imidazo[4,5-c]pyridin-2(3H)-one.



Yu *et al.* does not disclose 1-cyclopropyl-3-[1-(4-hydroxybutyl)-1H-benzoimidazol-2-ylmethyl]-1,3-dihydro-imidazo[4,5-c]pyridine-2-one.



Accordingly, Applicants respectfully submit that the pending claims are not prima facie obvious. Applicants therefore respectfully request reconsideration and withdrawal of these obviousness rejections as they relate to claims 1-24, 26-31 and 34-45.

Claim Rejections - Obviousness Type Double Patenting

Claims 1-8, 12, 16-19, 23, 24, 26, 29-31 and 34 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-8, 23-24, 29-31 and 34 of copending Application No. 10/593,382.

Applicants note that the foregoing rejections are provisional in nature and respectfully submit that they will be further addressed when appropriate, i.e., when the non-statutory obviousness-type double patenting rejection is the only rejection remaining in the later-filed application (MPEP § 804 I(B)).

Claim Rejections Under 35 U.S.C. § 112

Claim 35 stands rejected under 35 U.S.C. § 112 on the basis that the specification “does not reasonably provide enablement for *prevention* of an RSV infection” (emphasis added). Applicants respectfully disagree.

However, solely for the purpose of expediting prosecution, claim 35 is herein amended to remove the term “preventing”. At least in view of this amendment, Applicants submit that the outstanding rejection is herein rendered moot. Consequently, reconsideration and withdrawal of this rejection are respectfully requested.

Conclusion

It is Applicants’ understanding that no fees are due. However, should any fees be necessary, the Director is hereby authorized to charge any deficiency in the fees filed, asserted to

be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-4876, under Order No. 117750-01801.

If a telephone conversation with Applicants' attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned attorney at (617) 449-6500.

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Respectfully submitted,

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